

### **REMARKS**

Claims 1-9, 11-15, 17, 18, 20-48, 50, 52-73 and 75-93 are now pending in the application. The Examiner is respectfully requested to reconsider and withdraw the rejections in view of the amendments and remarks contained herein.

### **EXAMINER INTERVIEW SUMMARY**

Applicants kindly thank the Examiner for participating in an Interview on June 5, 2009. During the Interview, the pending rejections and the prior art references were discussed. Applicants noted that none of the prior art references teaches tracking multiple tracking devices at the same time. The Examiner agreed and suggested making amendments to the claims to clarify this point of distinction. As seen above, Applicants have clarified the claims as requested. The amended claims are of the same scope as previously presented and, thus, should not require additional searching. The Examiner indicated that the rejections under 35 U.S.C. § 103 may be overcome based on the amendments and the arguments presented below.

The objection to claim 80 was also discussed during the Interview. Applicants suggested that claim 80 could be amended to clarify that the structural differences comprise different shapes for each tracking element. The Examiner indicated that the objection may be overcome based on the suggested amendment and the arguments presented below.

Based on the Interview, Applicants believe that the application is condition for allowance. After review of this Amendment, if the Examiner believes any of the claims are not in condition for allowance, Applicants respectfully request that the Examiner

telephone the undersigned at (248) 641-1600 in order to expedite prosecution of this application.

#### **CLAIM OBJECTIONS**

Claim 80 has been objected to because of the following informality: the Examiner contends that the language "the tracking elements are structurally different..." does not explicitly define what the structural difference is (See Final Office Action at pages 3-4). Applicants have amended claim 80 in order to clarify that the first and second tracking elements have different shapes. Applicants respectfully request that the Examiner withdraw his objection to this claim.

#### **REJECTION UNDER 35 U.S.C. § 103**

Claims 1-9, 11-15, 17-18, 22-30, 33-44, 47-48, 50, 52-73, 77-80, 82, 85, 88 and 92 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Foley et al. (U.S. Pat. No. 6,226,548; hereinafter "Foley") in view of Ellis (U.S. Pat. Pub. No. 2003/0011624; hereinafter "Ellis"). This rejection is respectfully traversed.

Applicants respectfully submit that none of the cited references, whether considered alone or in combination with each other, teaches:

- (1) the tracking of a first localization or tracking element attached to a first implant member while also tracking a second localization or tracking element attached to a second implant member, as provided for by independent claims 1, 33 and 53; or

- (2) the tracking of a tracking element attached to a first implant member while also tracking a navigable instrument, as provided for by independent claims 22 and 67.

The Examiner asserts that, for each of the independent claims, the Foley reference teaches all of the elements except for an imageless procedure, for which the Examiner relies upon Ellis (See, e.g., Final Office Action at pages 5-15). Applicants respectfully disagree.

The Examiner is correct that the Foley reference teaches only an image-based procedure (See, e.g., Final Office Action at page 5). In Foley, an image is taken of a patient anatomy to which a fiducial array has been attached (See Foley at column 8, lines 9-26). This image is then loaded into surgical navigation system processor (Id.). The patient is then moved into the operating room and the patient anatomy is then registered to match the stored image, which may require image or anatomy manipulation (See Foley at column 8, lines 9-26 and column 9, line 64 to column 10, lines 2). An implant, or portion thereof, is then navigated based on the position of the patient anatomy as registered with respect to the stored image (Id.).

Each of independent claims 1, 22, 33, 53 and 67 provide for a system or method for tracking a first localization or tracking element attached to a first implant member while also tracking (1) a second localization or tracking element attached to a second implant, or (2) a navigable instrument. In this manner, the real-time positions of the first and second member/navigable instrument may be tracked and used throughout the procedure to assist in the final placement of the implant (See Application at paragraphs [0088] and [0116]).

Referring now to claim 1, Applicants respectfully submit that Foley does not disclose "a processor configured to ... track said first localization element fixed to said first member while tracking said second localization element fixed to said second member" as provided.

Referring now to claim 22, Applicants respectfully submit that Foley does not disclose a "processor [that] is configured to track the tracking element fixed to said first member while tracking said navigable instrument" as provided.

Referring now to claim 33, Applicants respectfully submit that Foley does not disclose "navigating the third member relative to the first member and the second member, while tracking the first tracking element connected with the first member and tracking the second tracking element connected to the second member" as provided.

Referring now to claim 53, Applicants respectfully submit that Foley does not disclose "a method of implanting a construct of at least a first member, a second member, or a third member substantially at least one of percutaneously or minimally invasively" comprising "tracking the position of the first member or the second member in order to provide a dynamic reference frame" as provided.

Referring now to claim 67, Applicants respectfully submit that Foley does not disclose a "processor [that] is configured to track said tracking element attached to the first member while tracking said navigable instrument" as provided.

Even if Foley were combined with Ellis, the combination would not teach the invention as provided for by the claims above. The Examiner relies upon the Ellis reference solely for its alleged teaching of an "imageless" procedure (See, e.g., Office Action at pages 6-7). Applying the teachings of Foley in an "imageless" procedure,

even if possible, would not provide the tracking of a first element while tracking a second element as claimed. Neither Foley nor Ellis, whether considered alone or in combination with each other, teaches the tracking of a first localization element or tracking element attached to a first implant member while tracking a second localization element or tracking element attached to a second implant member as provided by all of the claims.

Essentially, the Foley reference is directed to a system and method in which position information of a portion of an implant is determined by a pre-operative scan and, then, by a registration of the position during the procedure (See Foley at column 9, line 44 to column 10, line 2). Another portion of the implant is then guided to the position of the portion of the implant, as saved by the registration process, by use of the navigation system (See Id. at column 10, line 62 to column 11, line 3). The present claims, in contrast, relate to a system and method in which each portion of the implant is tracked by the navigation system at the same time (See claims 1, 22, 33, 53 and 67 above). Neither Foley nor Ellis teach this aspect of the claims.

Applicants therefore respectfully submit that independent claims 1, 22, 33, 53 and 67 are patentable over the cited references. As claims 2-9, 11-15, 17-18, 23-30, 34-44, 47-48, 50, 52, 54-66, 68-73 and 77-80 depend upon and include the limitations of one of the independent claims, Applicants submit that these claims are also patentable over the cited reference for the same reasons. Applicants request that the rejections under Section 103(a) be withdrawn.

Claims 20-21, 31-32, 45-46 and 75-76 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Foley in view of Ellis, as applied to claims 1, 22, 33 and 67,

and further in view of Acker et al. (U.S. Pat. No. 6,332,089; hereinafter "Acker"). Claims 81, 84, 87, 90 and 91 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Foley in view of Ellis, as applied to claims 1, 22, 33, 53 and 67, and further in view of Rasche et al. (U.S. Pat. Pub. No. 2001/0034480) ("Rasche"). Claims 82-83, 85-86, 88-89 and 92-93 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Foley in view of Ellis, and further in view of Shluzas (U.S. Pat. No. 6,648,888) ("Shluzas"). These rejections are respectfully traversed.

As stated above, Applicants respectfully submit that independent claims 1, 22, 33, 53 and 67 are patentable. As claims 20-21, 31-32, 45-46, 75-76 and 81-93 ultimately depend upon and include the limitations of independent claims 1, 22, 33, 53 and 67, Applicants submit that these claims are also patentable over the cited combination for the same reasons. Applicants request that the rejection under 35 U.S.C. § 103(a) be withdrawn.

#### **CONCLUSION**

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the outstanding Office Action and the present application is in condition for allowance. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the Examiner

believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (248) 641-1600.

Respectfully submitted,

Dated: July 22, 2009

By: Richard W. Warner  
Richard W. Warner, Reg. No. 38,043  
Michael A. Schaldenbrand, Reg. No. 47,923

HARNESS, DICKEY & PIERCE, P.L.C.  
P.O. Box 828  
Bloomfield Hills, Michigan 48303  
(248) 641-1600

RWW/MAS/gmp